Part of Paper #4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Slater	
v.	INTERFERENCE NO. 103,765
Rydell	Administrative Patent Judge Pate

DECLARATION OF MARK A. RYDELL

I, Mark A. Rydell, declare and say that:

1. I have reviewed United States Patent 5,352,222 and the Count of the above-captioned interference. I am the sole inventor of the bipolar electrosurgical scissors described and claimed therein.

2. Attached hereto as Exhibit A is a copy of my Curriculum Vitae. As indicated therein, I was an employee of Everest Medical Corporation between 1988 and 1993, serving as Vice President of Research and Development. Upon leaving Everest Medical Corporation as an employee in 1993, I continued to serve as a consultant to that company from 1993 to the present.

3. During my employment at Everest Medical Corporation, I made it a practice to keep a daily log of activities in three-ring spiral bound notebooks. On those occasions where I concluded that I had made a potentially patentable invention, I would record same in the company-provided "Laboratory Notebook". In my daily log (Book #4) for the period 2-26-91 to 12-16-91, there is an entry dated 8-26-91, a copy of which is attached as a

Exhibit B. It describes a bipolar scissors design in which both blades were anodized aluminum. The anodizing was ground away adjacent the cutting edges of the blades to expose the underlying metal that function as electrodes. I actually built scissors using this approach in late August 1991. It is submitted as evidence that I was working on bipolar scissors as of the date indicated. Attached hereto as Exhibit C is a collection of pages from my "Book #4" showing continuous activity in designing and developing a bipolar electrosurgical scissors in the fall of 1991, utilizing the anodized aluminum blades. The entry dated 9-27-91 and 11-4-91 referring to a "composite blade" was one designed to have a ceramic insulator as a cutting surface, the ceramic insulator being attached to metal blade supports which served as the coagulating electrodes.

4. On December 4, 1991, I made an entry on page 22 of Laboratory Notebook 21 of a bipolar electrosurgical scissors design for cutting and coagulating tissue. This entry is attached hereto as Exhibit D. The instrument depicted in Exhibit D has first and second blade members, each having an inner shearing surface and a conductive portion, where at least one of the blade members comprises a laminated assembly of an inner metal blade defining the inner shearing surface, an intermediate electrically insulative layer and an outer metal conductive layer forming the conductive portion that is electrically insulated from the inner metal blade by the intermediate electrically insulative layer. It included a means for pivotally joining the

first and second blade members with their respective inner shearing surfaces facing one another. The push rod coupled from the movable blade is used to impart a scissors-like movement relative to the other (fixed) blade member. The push rod is conductive and surrounded by an insulating tube to prevent it from shorting out against the inside wall of the tubular barrel. The push rod is adapted to be connected to a first terminal of an electrosurgical generator and the barrel to a second terminal of that generator whereby a voltage is developed between the movable blade and the conductive portion of the stationary blade, as well as between the inner metal blade and the outer metal conductive layer of the stationary blade.

5. On December 4, 1991, I prepared more formal drawings of the scissors shown on Exhibit D using the CAD system at Everest Medical Corporation. Prints of these drawings are attached as Exhibit E.

6. Between December 4, 1991, and December 13, 1991, I actually built and performed preliminary tests on a scissors conforming to what is described in paragraph 4 hereof and depicted in the drawings of Exhibit E. Recent photographs of the scissors which I built and tested in December 1991, are attached as Exhibits F-1, F-2 and F-3. As can be seen in the photos, the instrument included an elongated tubular metal barrel having a stationary handle member affixed to its proximal end and a scissors blade assembly affixed to its distal end. The blade assembly included a fixed blade and a movable blade, where the

movable blade was pivotally mounted to the fixed blade and connected by a push-rod to a movable handle member pivotally joined to the stationary handle member, such that when the movable handle member was actuated, a scissors-like movement was imparted to the blades. A close examination of the photos shows that the movable blade was a single piece of metal ground to exhibit a hook-shaped cutting edge and a planar shearing surface. The fixed blade included an inner metal blade member formed from stainless steel shim stock, an intermediate electrically insulative layer of polysulfone plastic, and an outer metal conductive layer. The inner metal blade, the insulating layer and the outer metal conductive layer were bonded together with a cyanoacrylate adhesive. Electrical connections were made to the movable blade and to the outer metal conductive layer on the stationary blade, allowing a voltage to be applied across them.

7. On or about December 13, 1991, I tested the scissors in a lab at Everest Medical Corporation by cutting beef steak and determined that it both cut the meat and seared it on both sides of the cut line. Co-workers at Everest Medical Corporation to whom I demonstrated its performance included David Parins, Joseph O'Brien, Michael Hollenhorst and possibly others whom now I cannot specifically recall.

8. On December 19, 1991, I had the opportunity to test the scissors of Exhibit F in a live animal in the University of Minnesota Medical School Animal Laboratory. I was accompanied by my coworker, Joseph O'Brien. Also present was Myra Urnas, a

University of Minnesota medical technician in the Animal Laboratory. These two individuals witnessed the ability of the bipolar scissors described above in paragraph 6 to both cut through tissue and to simultaneously coagulate cut tissue to prevent bleeding. We used the occasion to test the scissors on a variety of tissues, including bowel, fat and fasciae. We determined that the scissors was effective in coagulating the tissue to stem blood flow and, that while in cutting some tissues, like fasciae, the cutting performance was somewhat poor, with bowel tissue and fat, it was fairly good. Attached hereto as Exhibit I is an entry from my daily log (Book #5) for December 19, 1991, reporting on the tests performed at the University of Minnesota Medical School Animal Laboratory.

9. Based upon the testing on a live animal on December 19, 1991, I was satisfied that the scissors carried out its normal intended function of both cutting and coagulating tissue, even though improvements still had to be made before it would serve as a commercially successful disposable, single-use electrosurgical scissors. We were convinced from the testing that we carried out that the scissors instrument described above in paragraph 6 successfully demonstrated its utility in a surgical procedure to both cut and achieve hemostasis by electrocoagulation.

10. Attached hereto as Exhibit G is a monthly status report, dated January 3, 1992, which was submitted to the President and C.E.O. of Everest Medical Corporation, reporting on the December 19, 1991 testing of the scissors described in

paragraph 6 hereof. In stating that it "did not cut well" I meant that the cutting ability was not yet up to a standard required for commercial introduction.

11. Following the testing described above in paragraph 8, I along with others at Everest Medical Corporation continued to explore several other design approaches for implementing a bipolar electrosurgical scissors during the period from January 1992 through December 1993. One such approach was to affix ceramic cutting blades to metal blade supports and then apply a voltage between the metal blade supports for coagulation. This is the configuration described in my U.S. Patent 5,514,134. We marketed this design and were advised by surgeons that bipolar electrosurgical scissors for laparoscopic use should preferably have a curved blade configuration so that the surgical field viewed through a camera would be less obscured than with a straight blade. We determined that it was too costly to create arcuate ceramic coupons for attachment to curved blade holders and our experience led us to conclude that this scissors design with curved ceramic blades had various practical problems that could not be rectified at reasonable cost and within a time frame necessary to sustain sales. It was in December 1993 that we devised a bipolar electrosurgical scissors having curved blades. These curved blades were a composite laminate of metal on metal, of the type I earlier built and tested in December 1991. This became the preferred embodiment and best mode described in my U.S. Patent 5,352,222 involved in the present interference.

Attached hereto as Exhibit H are drawings which I have prepared on or about December 9, 1993. The laminated blade configuration shown therein is substantially the same as I used on the hook scissors which I built and tested in December 1991, as related in paragraphs 6-8, *supra*, except that in the drawing of Exhibit H, the blades are curved rather than straight. Everest Medical Corporation began sales of electrosurgical scissors in accordance with Patent 5,352,222 in March 1994.

12. I hereby state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above application or any patent issuing thereon.

Further affiant saith not.

Dated: Sept 30, 1998.

Mark A. Rydell

Exhibit A

Mark A. Rydell
516 Turnpike Road
Golden Valley, Mn 55416

Education:

Gustavus Adolphus College 1972
B.A. Degree - Economics

Work Experience:

Advanced Bio-Surfaces, Inc. Design Engineer
Develop instruments of use in resurfacing articulating joints.

Rydell Design, Inc.
1995 - Present President
Medical device design, consulting, prototyping, process development, and testing.

Angiomedics II, Inc.
1993 - 1995 Senior Design Engineer
Performed animal research on the effects of ultraviolet light for inhibiting restenosis following damage to artery by balloon catheter.

Everest Medical, Inc.
1988 - 1993 V.P. of Research and Development
Developed endoscopic electro-surgical devices.
Bipolar polyp snare, Bipolar GI coagulator, Bipolar laparoscopic forceps, Bipolar laparoscopic scissors, and various other cutting and coagulating instruments.

Gull Medical Products, Inc.
1993 - 1996 Owner
GMP produced OEM catheters and assemblies for the US and international medical device markets. GMP was sold to TFX Medical Inc.

Angiomedics, Inc.
1983 - 1984 Founder, co-inventor and Design Engineer responsible for design and testing of Soft Tip catheters.
1984 - 1985 Mechanical engineer responsible for developing processes for manufacturing catheters.
1986 - 1989 Manager of Advanced Design
Developed line extensions of original Soft Tip catheters.
Developed guiding catheters and method of manufacture.
Developed balloon catheters and method of manufacture.
Developed accessory equipment.
Worked on stent delivery system for Pfizer stent.
Worked on transfer of technology between US and European division.

In 1986 Angiomedics was sold to Pfizer for $70 million, and renamed Schneider.

Cathedyne Corporation
1981 - 1983 V.P. and Design Engineer.
Performed research on developing a balloon angioplasty system which was safer and more effective.

Automation Machinery Builders, Inc.
1973 - 1980 V.P. and General Manager
Designed and built machinery for plastic processing companies.

Accomplishments:

Holder of 47 patents on medical devices.
Listed in 22nd edition of Who's Who in the Midwest.
Softip Catheter named product of the year in 1987 by Medical Alley Association.

Publications:

A Less Traumatic Catheter for Coronary Arteriography.
Comparison of Monopolar vs. Bipolar Sphincterotomes.

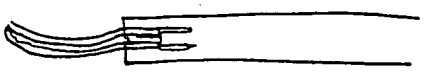
Consulting Clients:

Medtronics
Optical Sensors
OncoCath
Advanced Bio Surfaces
Everest Medical
Contimed
Cardiac Instruments
Circulation, Inc.
Urologix
Cardia Catheter Corp.
Latis, Inc.
Tri Cardia
Anova
SpectraScience
TFX Medical
Thermaseed
Micro Quest Diagnostics
Schneider, Inc.

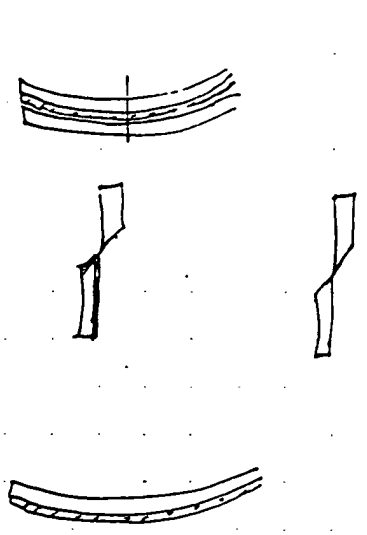
Exhibit B

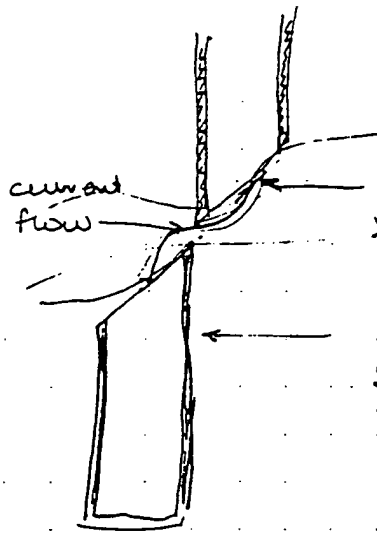
8-26-91

bipolar scissors



US surical design





hardcoated aluminum

grind through coating to provide coag surface.

aluminum oxide surface provides insulation.

could flame spray Al. oxide also.

disclosed loop grasper to T. Nikolai
bipolar forceps
bipolar scissors

product Development meeting

trumpet valve by ACS - Oct 20-24
cleaning brushes - 10

Snare-

.050-.100

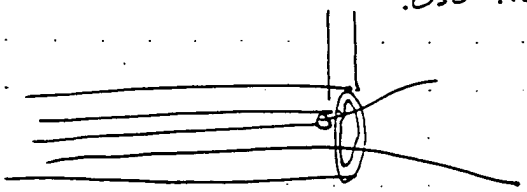


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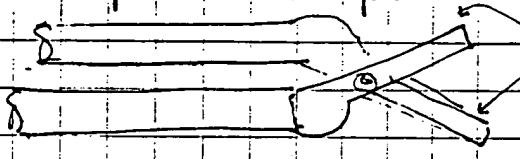
Exhibit C

Redacted

works on annealed gum paper

1-3-91

built experimental Bipolar scissors used aluminum tubing



tubenes like inner shaped blade

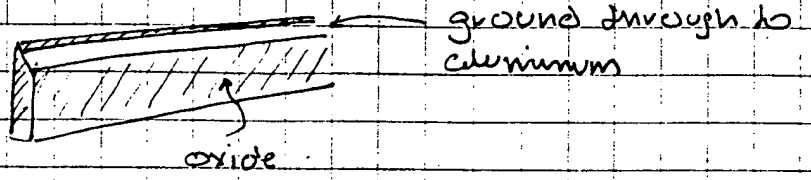
cuts paper ok.. needs to be anodized.

pin goes thru short handle

9-11-91

worked on scissors -
picked up parts from Pioneer yesterday

used krayton wheel on Dremel tool to grind away some oxide coating on blade



disclosed Bilap with interchangable tips to Tom Nikolai

worked on LEEP electrode

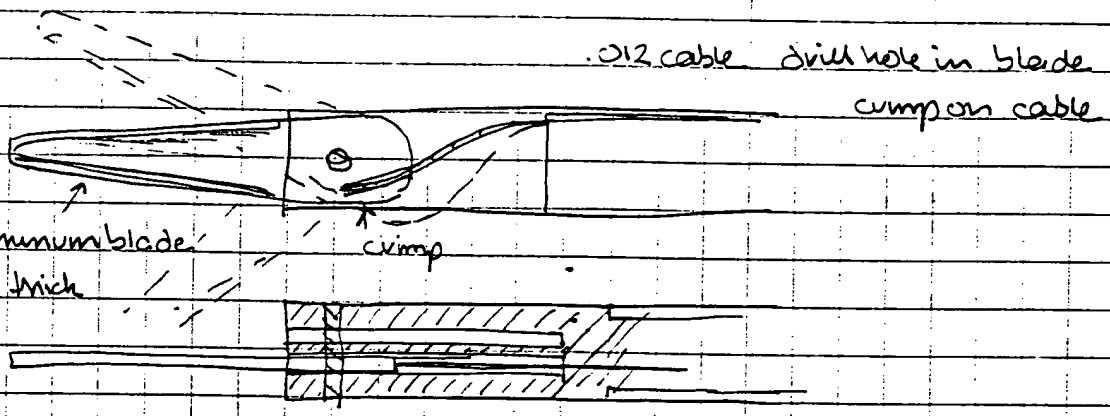
Redacted

9-13-91

tested bipolar scissors –

cut liver, started at 10 watts, little coag effect increased to 15 then 20 watts at 20 we got good coag effect both sides of cut were blanched. tissue sticking to aluminum surfaces reduces coag somewhat, but not to the point where coag stops.

tested scissors for shorts after cutting and found no shorting



aluminum anodized to make non-conductive, ground through anodizing to form electrode.

crimp to cable allows thinnest joint possible, still having strong joint. could also use traditional linkage, raise crimp suitable simulation of link.

9-16-91

Staff meeting –

<

+ width

scissors: tested aluminoxide coated blades, cut piece of liver in two got good blanching of liver on both sides of cut. testing ideas for mechanism.

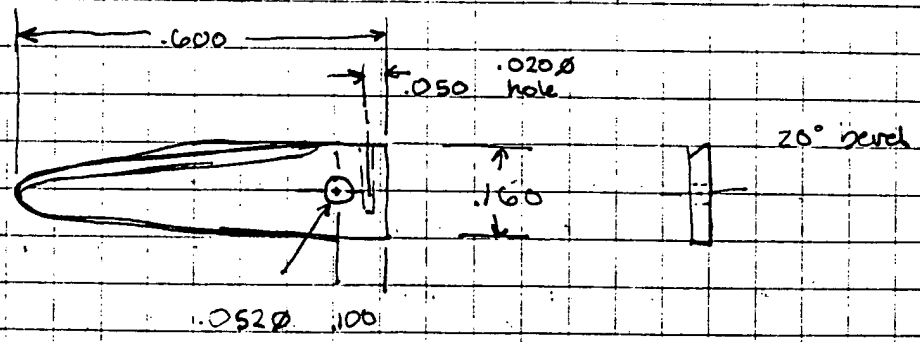
Redacted

9-17-92

Ordered slotting saws from Tool Crib called Pioneer -

6063 is best aluminum to use for maximum thickness of anodized layer. Thickness is about .0025"

6061 maximum thickness is .002"



bought 6061 x .040 sheet

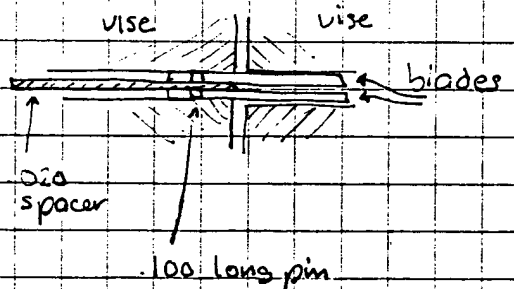
REDACTED

9-18-91

blade material—

6061 T4

9-19-91



put .020 offset in blades so spacer can be used between blades.
with .020 spacer in fixture we need a .015 spacer in device

tested experimental scissors again. cuts well at 25-30 watts at 35 sparking was evident. no damage was evident from sparking. problem occurs when device is wet with saline solution, then arcing occurs and causes damage to blades. dielectric is probably not thick enough.

redacted

9-26-91

dropped off scissors blades at Pioneer for anodizing

Shirley said that hard coat has a bigger dielectric ability than anodizing. harder to do though for small parts.

should use 6063 and have hard coated. hard coating has deeper penetration

sealing after anodizing is important it affects dielectric strength. can be sealed with wax solutions to increase lubricity.

9-27-91

worked on handle of scissors
met with Tom N. to start grasping loop patent
disclosed rotating feature
disclosed crimping of cable into aluminum
on scissors
picked up anodized blades for scissors

Redacted

Scissors: blades finished ~~came~~
assemble parts and test. need to figure out pin.

composite blade:

tungsten-ceramic prototype build will test this week.
getting quote on grinding of ceramic portion of
blade from specialist in grinding small parts.
aluminum with anodizing finished will test this
week.

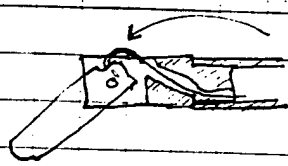
~~give~~ review to Steve

Redacted

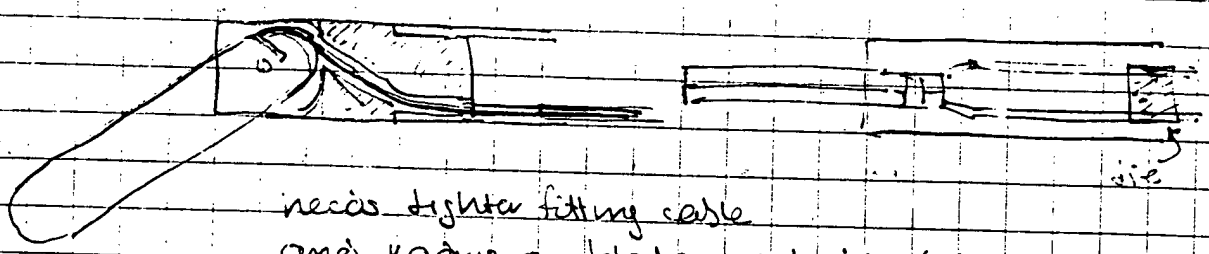
10-1-91

finished scissors -
blades open and close ok.

problem is not enough force can be put on blades



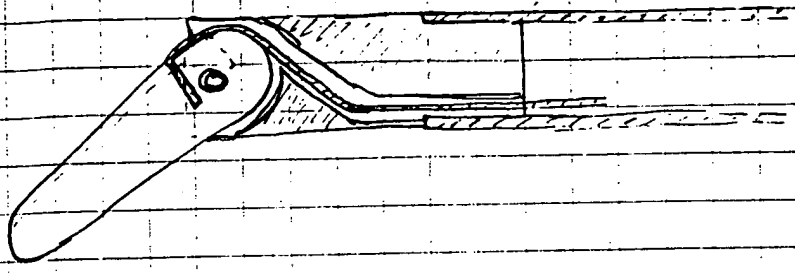
this loop acts as spring
to keep all the force from handle
from being applied to blades.

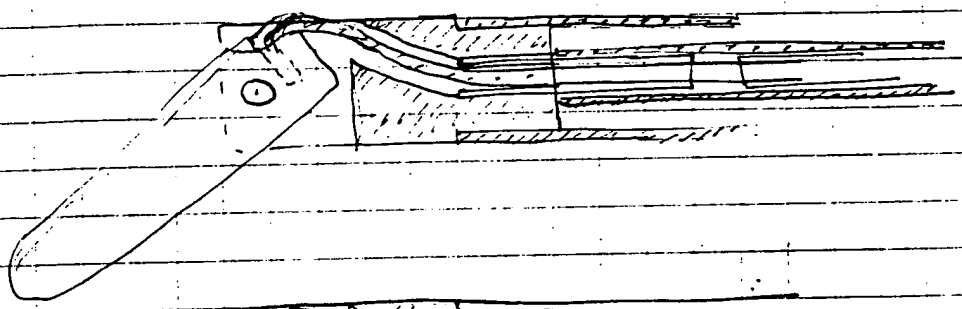


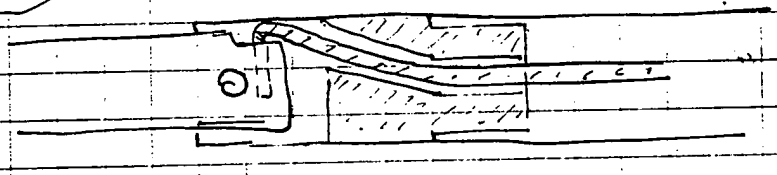
vie

needs tighter fitting cable
and washers on blade. get rid of loop
maybe use more flexible cable and run
ss needle tube closer to blades.
also tie cables together at distal end helps
also. keeps blade symmetrical and removes play.

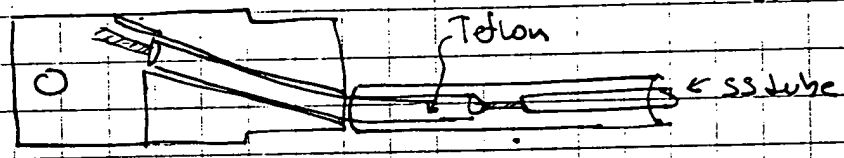
10-2-91







run ss tube to distal end.



channel should angle to back of part instead of knuckle only

10-3-91

made experimental blade with radius same as top drawing works well. good range of motion. same length of lever arm through entire swing of blade.

tested scissors in liver coagulates fine. would not cut very well though problem is too much play in cables.

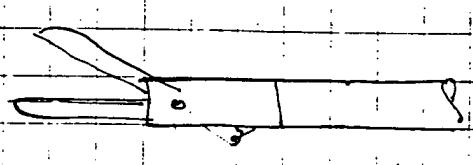
built new moulds and reground blades to use like top drawings

crimpins

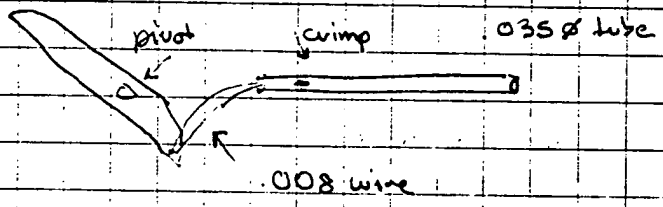
used hard steel pin, put in chuck on mill and pressed over cable crimp is localized. doesn't hurt pivot hole

10-15-91

built scissors with one fixed and one moveable blade.
used blades from first experimental scissors.
seems to work ok. blades are not very sharp but
they can put good pressure on.

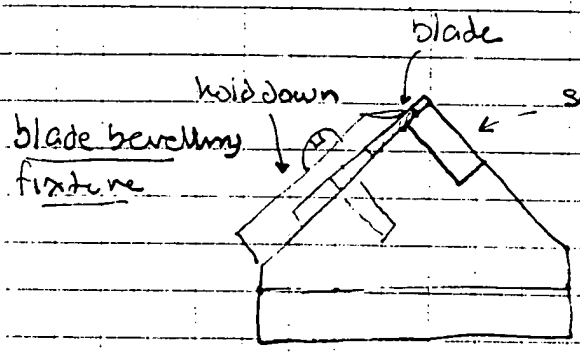


used snare handle



tested above device in liver - coagulation is good, but
cutting is poor.

built 3 new blade pairs.



10-29-91

worked on another Scissors for Thursday dog lab.

10-30-91

finished scissors
changed drawing on CAD

10-31-91

11-4-91

Staff meeting

n blade

could not
vary and
clean.

Scissors: worked ok in fat and soft tissue. cut so-so in bowel. tissue adhering to blades caused jamming
needs: · more positive mechanical action
· possible blade serrations
· none stick coating
cag was good no shredding

Composite blade:
parts in from grinder. prototypes being assembled.
Protocol to which

11-4-91

need - sheathed hockey sticks for Tom Leonard
generator for Tom.
spec. on sep

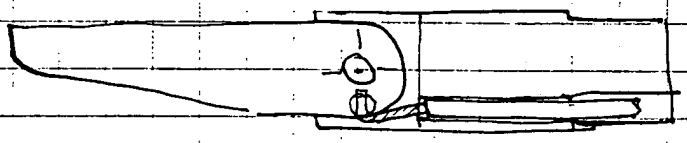
Product Development meeting

11-5-91

Redacted

11-7-91

Scissors



change crimp point to centered on hole
less cable length to buckle up when opening.

built above design works well can get cable to buckle up. when opening. still too much play in system, when blades are held closed. handle can still be moved.

Redacted

11-12-91

quote on scissors blades from Ellison

4.55 ea

227.50 for 50 pcs.

went to T. Nikolai to discuss scissors patent

11-13-91 built 3 Myotomy devices for Kevin

12-3-91 Staff meeting

Scissors: blades back from Ellison Machine
sharpened and sent out for coating
new handle designed and build. fixture board for
holding blade mounts during machining.
device downsized to fit through 4.8 inocoar
getting quotes on all machined parts.

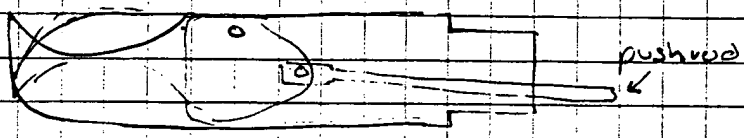
rework 6 - 8751
do we have the parts?
ask Scotland Lonestream to work extra to modify

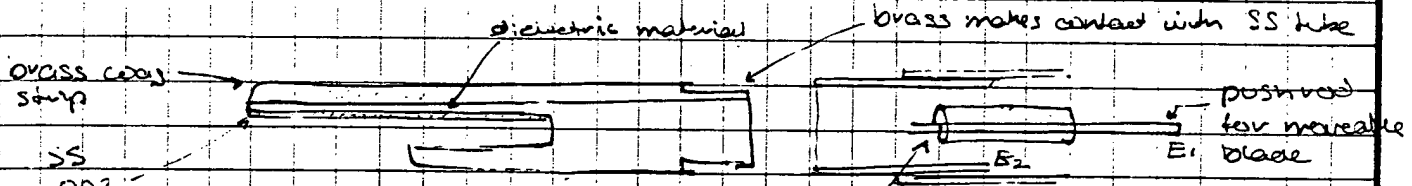
did drawings on scissors handle and
blade mount

Exhibit D

From Page No.

see cad drawings
12-4-91 B

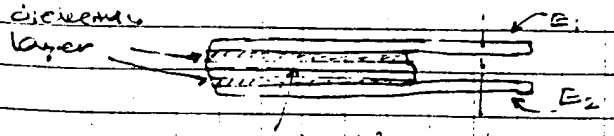




wide sleeve against SS laminate
tissue gets trapped between moveable blade and non moveable blade. moveable blade is on electrode, tissue contacts other electrode causing coagulation.

nonmoveable blade could also be made of ceramic with conductive trace, or insert molded in such a way as to provide coax strip.
use technology similar to Bard Hemoroid probe.

both blades could also be made as sandwich

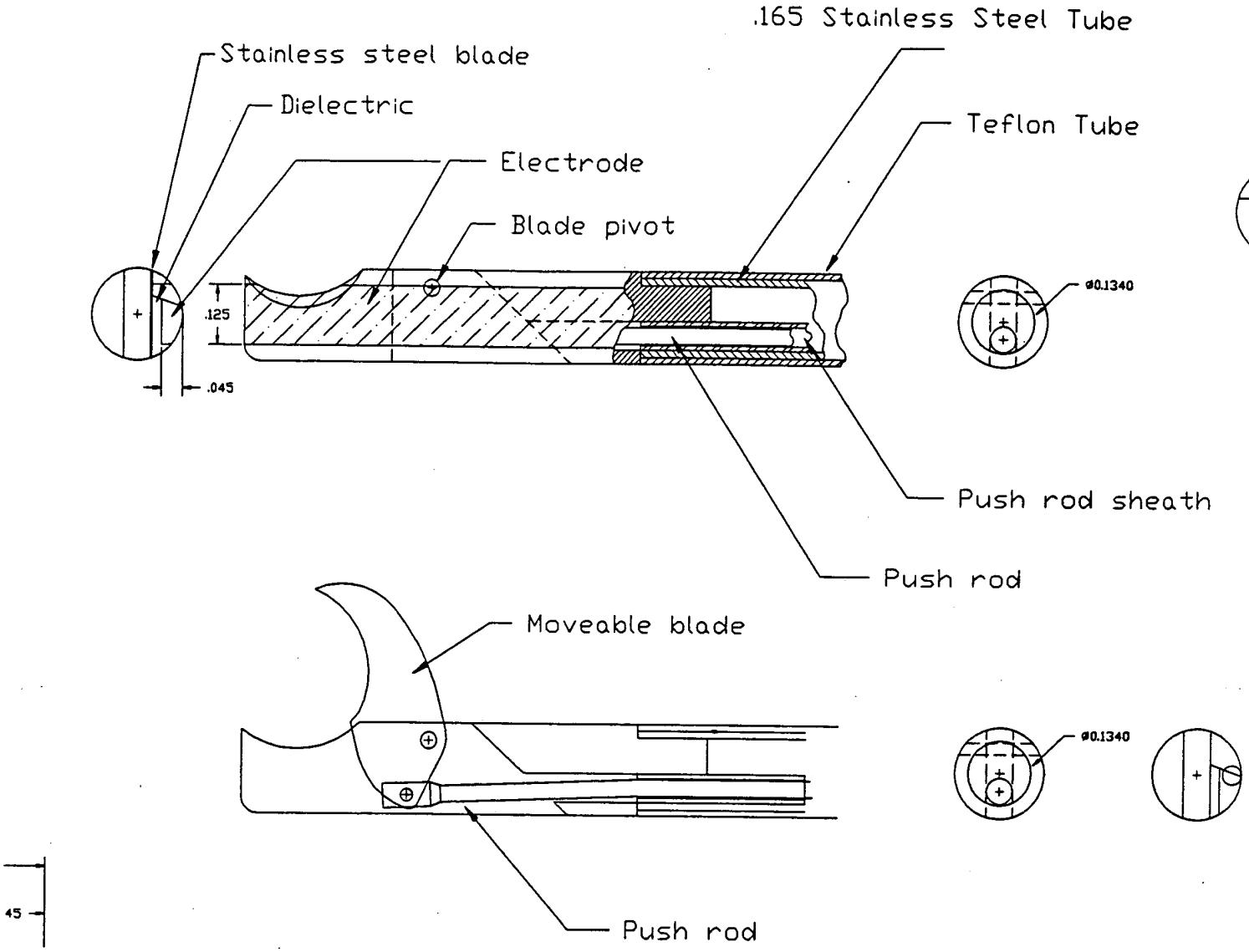


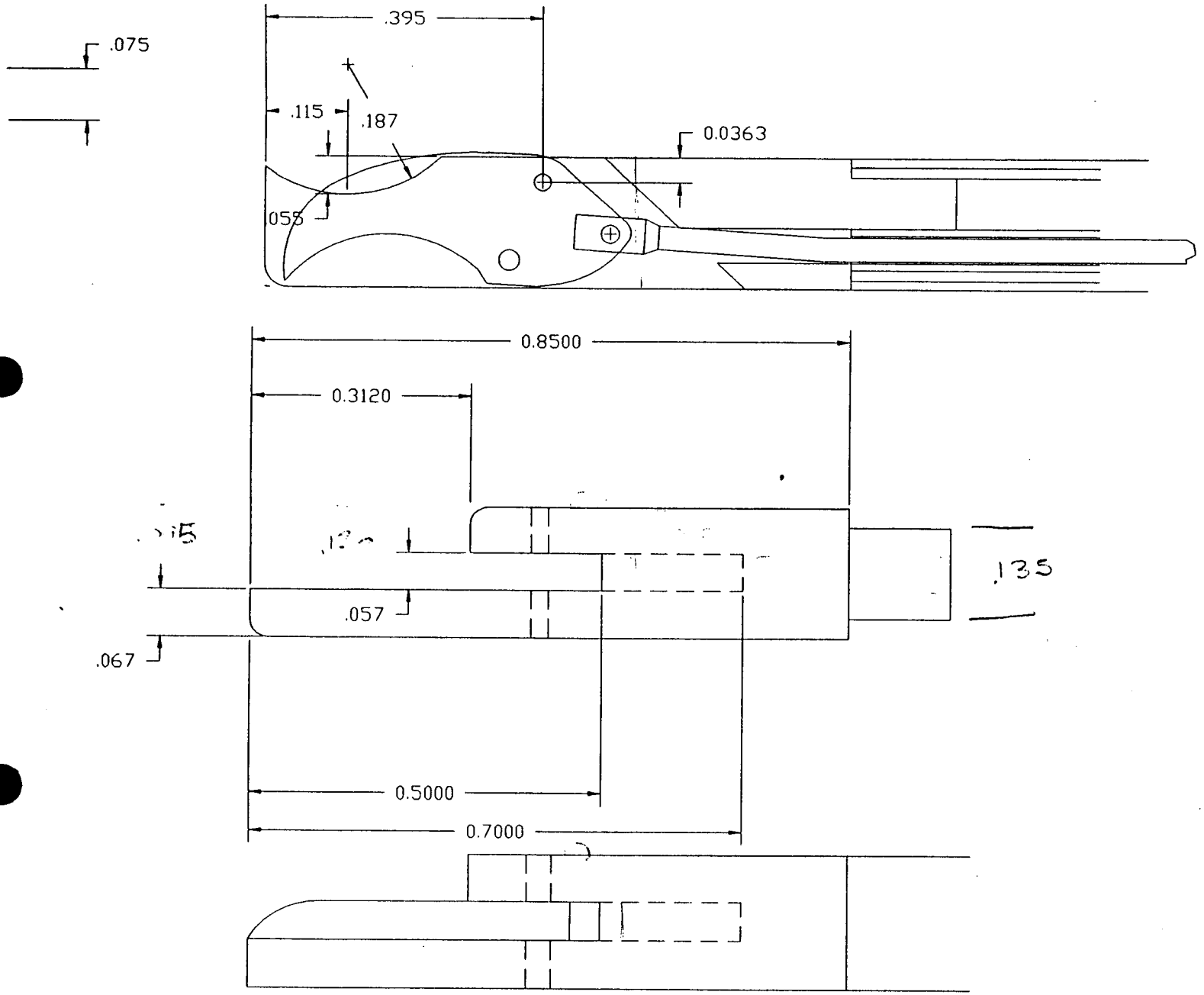
To Page No.

Witnessed & Understood by me,	Date	Invented by M. Rydell.	Date 12-4-91
		Recorded by	

Exhibit E

12-4-91B

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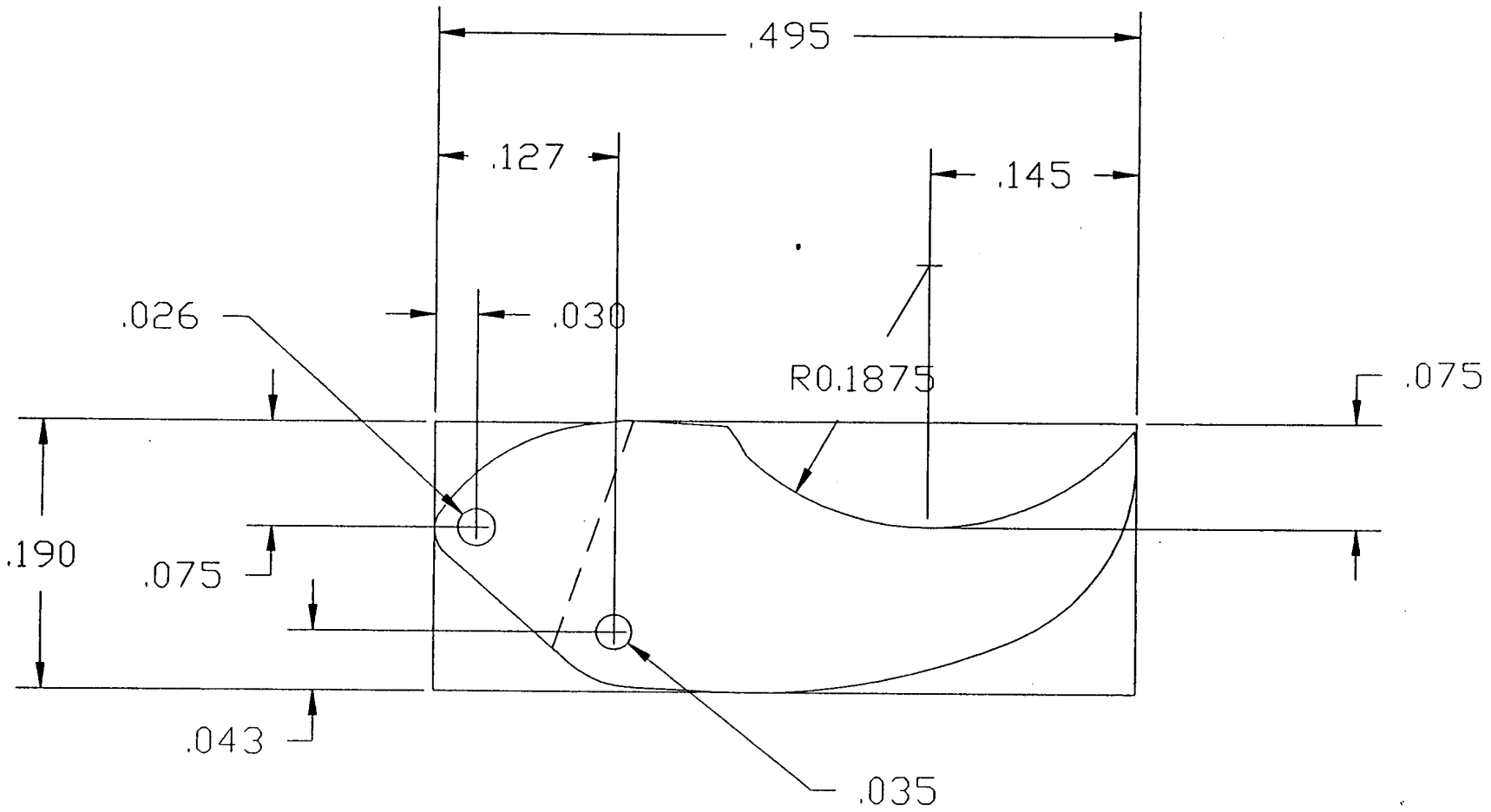
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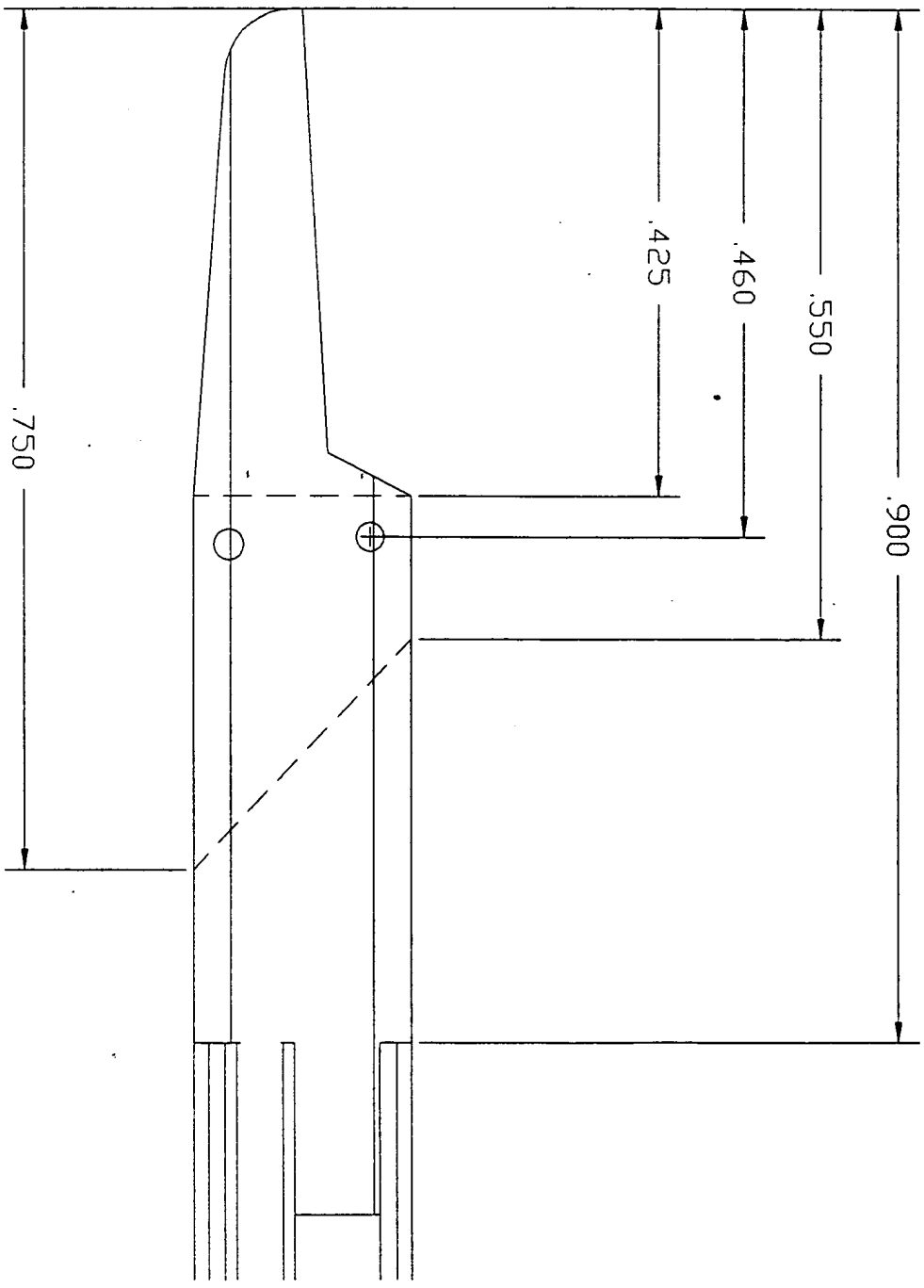
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.550
.900

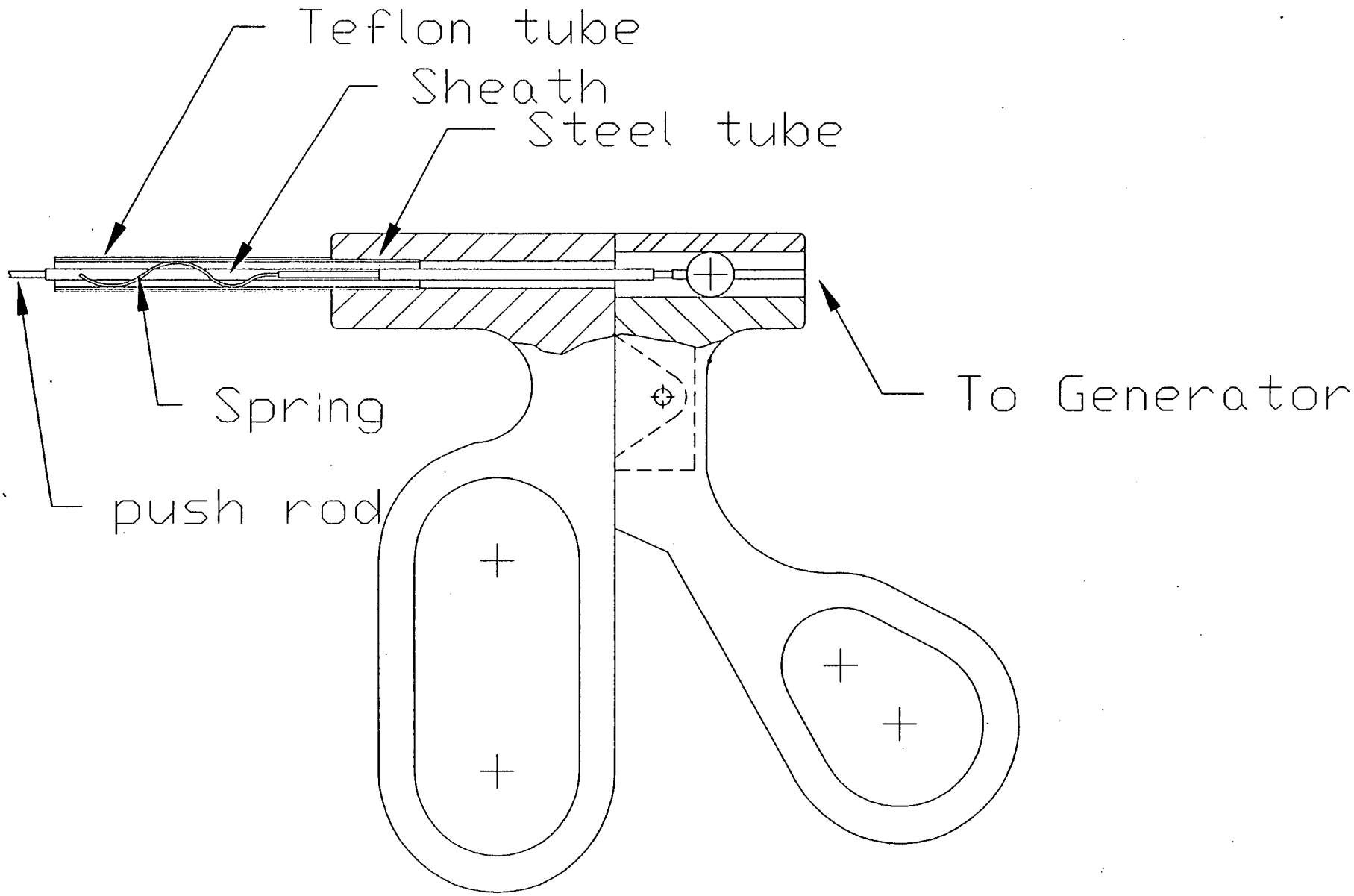

Teflon tube
Sheath
Steel tube
Spring
push rod
To Generator

Exhibit F1

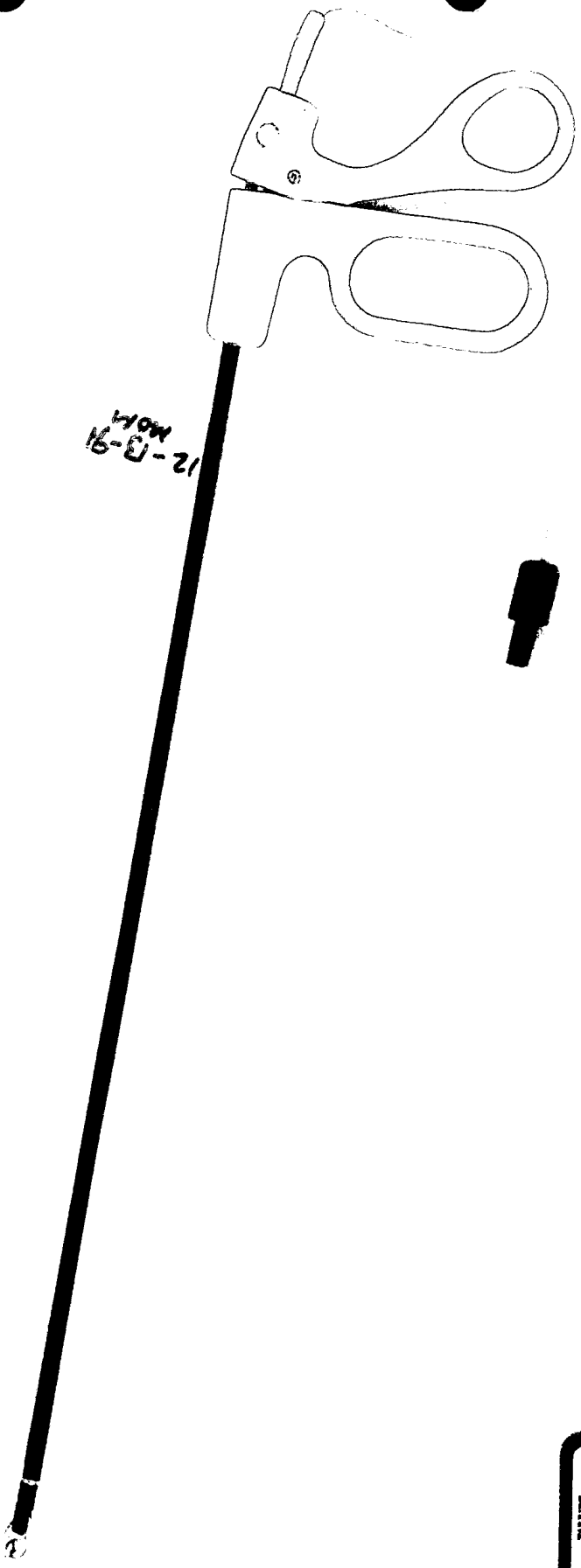


EXHIBIT
F-1
DECLARATION
OF MARK A.
RYDELL

Exhibit F2

EXHIBIT
F-2
DECLARATION
OF MARK A.
RYDELL

Exhibit F3

EXHIBIT
F-3
DECLARATION
OF MARK A.
RYDELL

Exhibit G

Michael Hollenhorst

Jan. 3, 1992

Mark Rydell

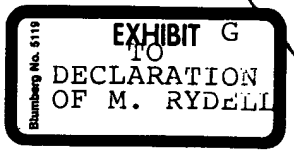
DEPARTMENTAL UPDATE

Present staff: Mark Rydell, Steve Berhow, Mike Baden, Greg Garlough

Present projects:

BiLAP

Redacted



Opportunities:
We have identified some good sources for the fitting.

SCISSORS

Status:
We tested three pairs of scissors in a dog lab. Aluminum oxide coated blades coagulated well but did not cut well. The steel-plastic composite blade also coagulated well, but did not cut well. I designed a new scissors with all steel construction and tested in steak. It cuts very well, but coagulated more on one side of the cut than the other. I built another device to address this problem and tested it in steak. This device cuts well and has more even coagulation. I designed and built a blade sharpening fixture. These two new scissors are available for use in a dog.

Issues:
The device started out as a single use disposable, but now seems to be evolving towards a reusable device. This is because of the difficulty involved in making a functional scissors. This, however presents new design problems because of the necessity of being able to clean and sterilize the instrument. My most functional scissors is not easy to clean.

Opportunities:
We have had both excellent cutting and coagulation with our scissors. We are currently trying to combine both functions in the same device. I will also be trying to develop another concept for a bipolar scissors.

Redacted

FORCEPS

Redacted

Exhibit #

Everest Medical

13755 First Avenue North
Minneapolis, Minnesota 55441-5444
612-473-6262 • Facsimile: 612-473-6465

December 9, 1993

Mr. Thomas Nikolai
Haugen & Nikolai, P.A.
900 Second Ave. S. Suite 820
Minneapolis, MN 55402

Dear Tom,

Enclosed are some drawings that better explain the idea I disclosed to you on Tuesday the 7th. As you can see the assembly is much the same as our ceramic blade design, including the plastic insulating bushings and the ceramic blade mounting hub. The ceramic blades, however have been replaced with the composite blades made by bonding a sharpened piece of spring steel with epoxy to the pivoting element. The blade material must by capable of holding an edge, and the epoxy must have a proper dielectric strength.

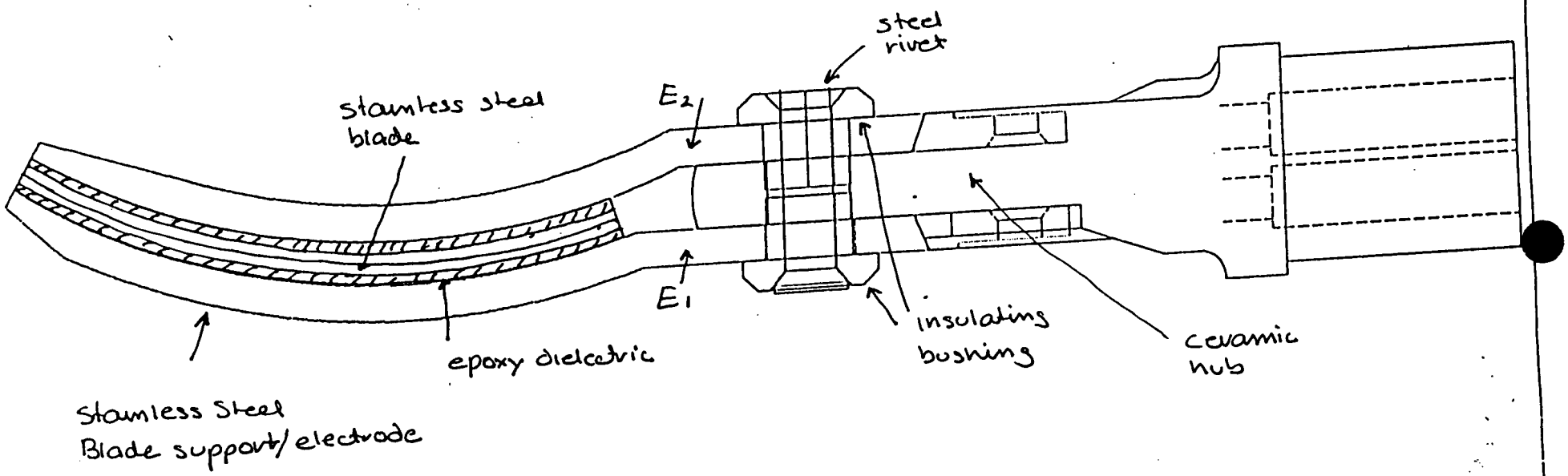
I will get back to you soon with filing instructions.

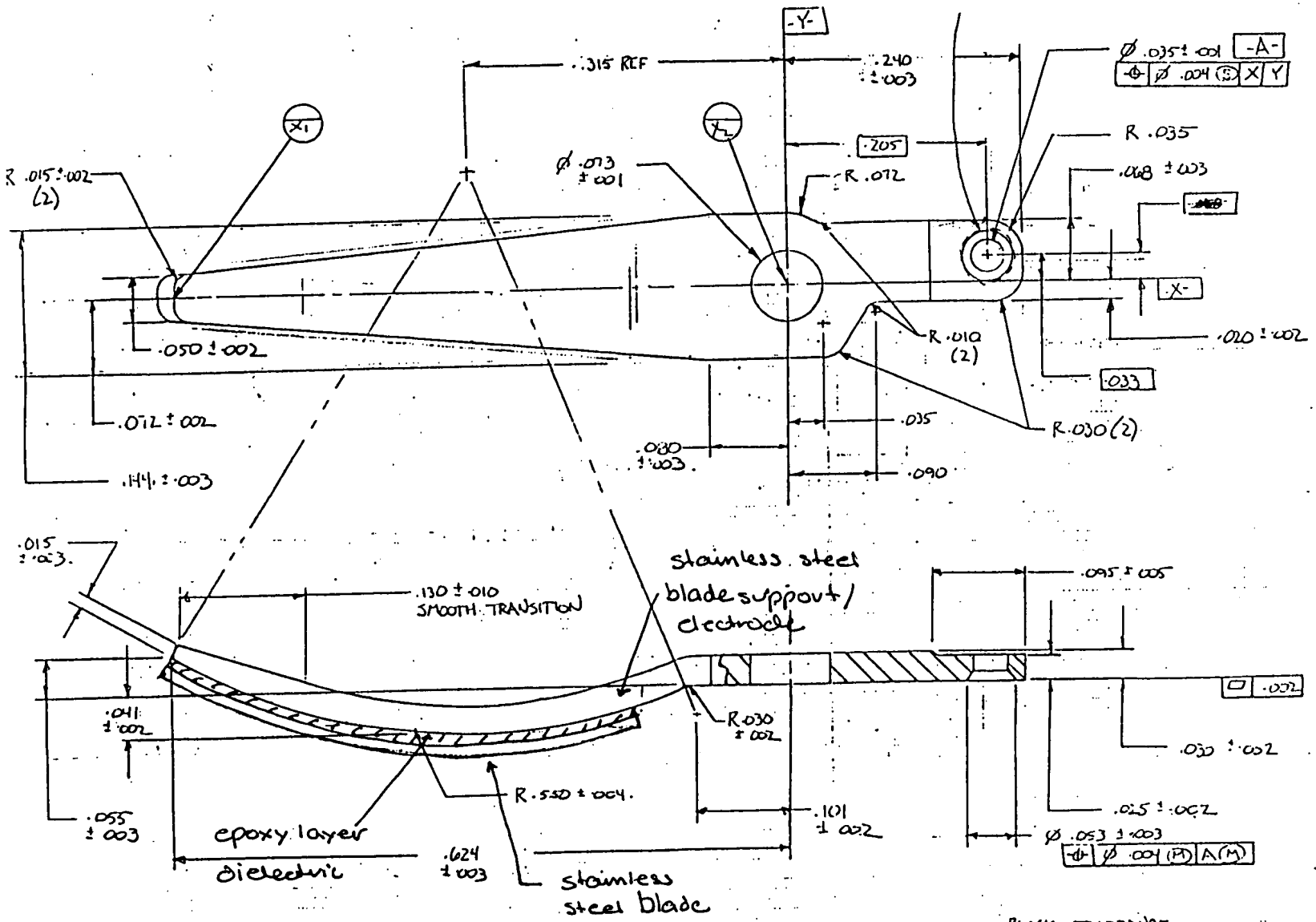
Best Regards,

Mark

Mark A. Rydell

EXHIBIT H TO DECLARATION OF M. RYDELL


steel rivet
stainless steel blade
E_2
E_1
insulating bushing
ceramic hub
epoxy dielectric
Stainless Steel
Blade support/electrode



NOTES:

1. MATL 304 SST (.030 THICK REF)
2. NO BURRS ALLOWED
3. PARTS TO BE DEGREASED
4. PARTS TO BE PACKAGED IN A MANNER SUITABLE TO PREVENT DAMAGE DURING SHIPPING.

Qty 2

BLOCK TOLERANCE

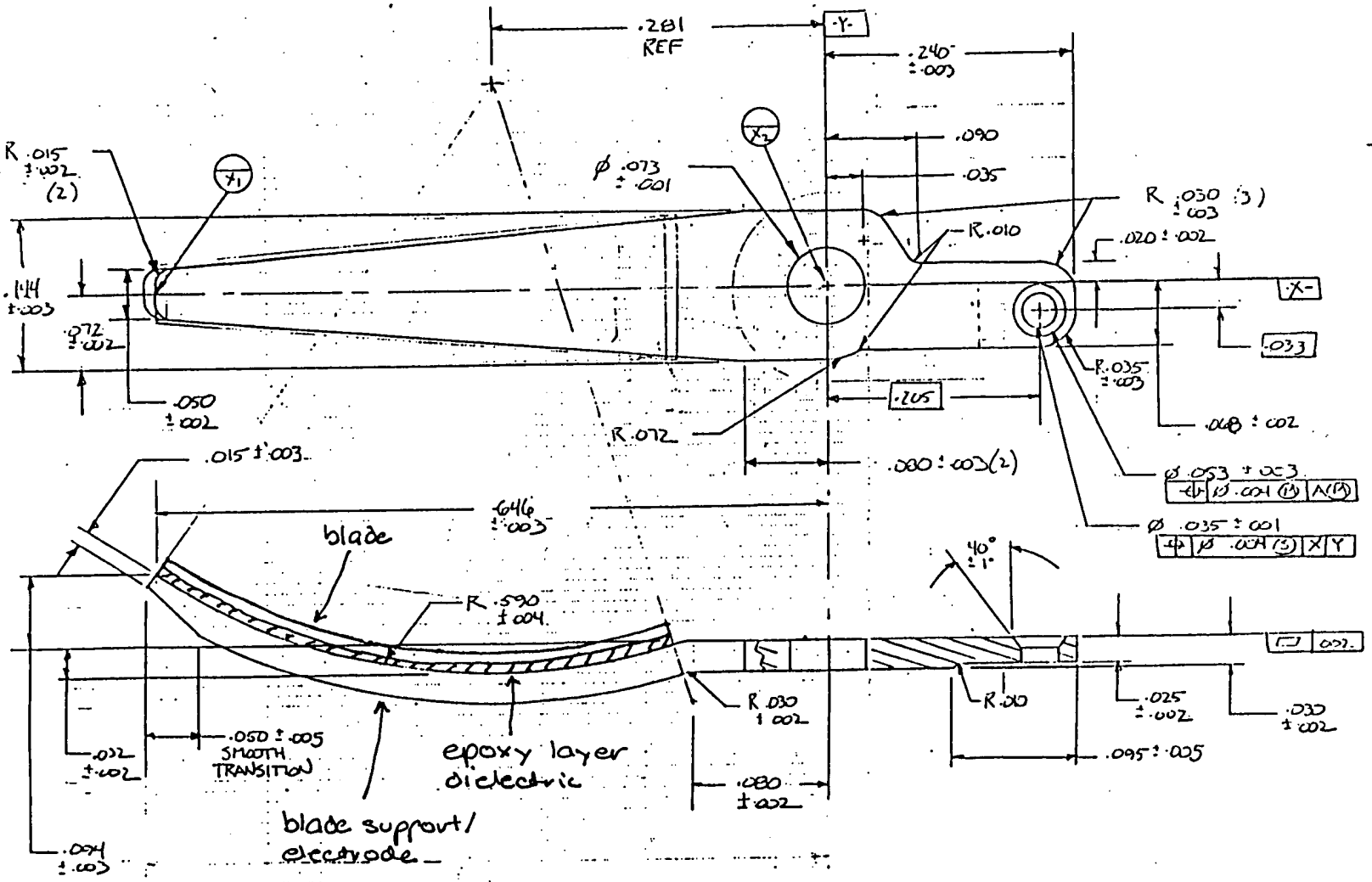
.XX ±.010 ANGLE ±2°
.XXX ±.002

PN 350192-001 REV 3

BLADE, SCISSORS, RIGHT

MODEL 3810

12/29/12
KFT



NOTES:

1. MATL 304 SST (.030 THICK REF)
2. NO BURRS ALLOWED
3. PARTS TO BE DEGREASED
4. PARTS TO BE PACKAGED IN A MANNER SUITABLE TO PREVENT DAMAGE DUR[illegible] SHIPPING.

Qty 2

BLOCK TOLERANCE	
.XX ±.01	ANGLE ± 2°
.XXX ±.002	

PN 350193-001 REV 5

BLADE, SCISSORS, LEFT

MODEL 3910

12/29/92 AKT

Exhibit I

12-19-91

Workman forceps -

dog lab at Jon M

tested scissors

no. 1 aluminox. ground off knife blade
did not cut as well as I would have liked. too dull.
had to pull tissue to get it to break.
coag was good.
tissue also didn't stick to blade much at all.

no 2 aluminox. partially ground off blade
not as good as above. poor mechanical cut.

no 3 hook. coag was good again could
be used like forceps by not tightening too hard
around tissue. still did not cut as good as
it should have.

I believe latex is a pretty good test.

tested cholangiogram device in ureter of dog
it was very easy to place, and held with when
released. we injected saline and easily filled
ureter.

Part of #4

HEADSUP Your Story Request ORDER NO. 9552348

EVEREST MEDICAL ANNOUNCES NOTICES OF ALLOWANCE FROM U.S. PATENT OFFICE; DISCUSSES RECENT DEVELOPMENTS IN PATENT STATUS

MINNEAPOLIS, July 21 /PRNewswire/ via INDIVIDUAL -- Everest Medical Corporation (Nasdaq: EVMD) today announced recent developments regarding the patent status of the company's laparoscopic bipolar scissors technology. The company reported that it has received official notice from the United State Patent Office that patents are to be granted for its second generation bipolar scissors design, EVERSHEARS(TM) II and on its bipolar scissors having curved ceramic blades.

In addition, the company has learned the Patent Office has recently issued two patents to another party involving bipolar scissors technology. After review of the allowed claims of these patents, the company, based on the advice of counsel, believes that its EVERSHEARS II bipolar scissors does not infringe either of these two patents. EVERSHEARS II incorporates an innovative metal-on-metal design with features that are superior to the ceramic scissors in design. However, the ceramic bipolar scissors currently being manufactured and distributed by the company may be covered by the claims of the other party's patents if those patents were properly awarded to that party. The company is currently evaluating its options regarding this product which include the commencement of an interference action brought by the other party based on the company's belief that it may have been the first inventor of the ceramic bipolar scissors technology.

According to John L. Shannon Jr., Everest president and chief executive officer, "We are pleased to announce the recent action by the Patent Office indicating the allowability of the company's patent on its second generation bipolar scissors design which is expected to provide higher reliability and improved margins. We believe we will be in a position to commence shipments of this product in the third quarter 1994." Shannon went on to say, "Although we are facing some uncertainty with respect to our ceramic bipolar scissors due to the recently issued opposing patents, we are confident that EVERSHEARS II presents the company with a very strong marketing alternative in the bipolar scissors market. Furthermore, at this time, Everest remains the only manufacturer offering a bipolar scissors of any kind to the minimally invasive surgery market. The patent to be granted on the curved ceramic blade adds to the company's defensive posture relative to future competitors."

Everest Medical is a leading designer, manufacturer and marketer of bipolar electrosurgery instrumentation for minimally invasive surgery markets. Everest Medical common stock is traded on the Nasdaq over-the- counter market under the symbol EVMD.

/CONTACT: John L. Shannon Jr. of Everest Medical Corporation, 612-473-6262/ (EVMD)

[07-21-94 at 16:53 EDT. PR Newswire, File: p0721165.100]

Part of #4

The Risks Of Using Monopolar Electrocautery In Endoscopic Procedures

It is well understood that the risks inherent in using monopolar electrocautery are far greater in endoscopic than in open surgical cases. On April 29, 1991 the Federal Food and Drug Administration held a hearing at the Hubert Humphrey Building in Washington D. C. on the use of monopolar electrocautery in endoscopic surgery.

BIPOLAR electrosurgical devices have both the electrodes between which the radio frequency high electrical voltages are impressed at the point of tissue cutting and current passes only through the tissues between the bipolar electrodes.

MONOPOLAR (or UNIPOLAR) electrosurgical devices have one small electrode in the instrument that the surgeon holds and the other electrode is a large plate beneath the patient. Accordingly, whenever monopolar devices are activated, electrical currents are passed completely through the patient's body.

CONCERNS about the risks of monopolar electrical currents during endoscopic surgery passing through the body and causing injury to vital structures both in the region near the operative site and remote from the operative area have been widely expressed and were recently discussed during an FDA Hearing on the subject of monopolar electrocautery.

SELECTED QUOTATIONS from the FDA Hearing regarding the risks of monopolar electrosurgical devices in endoscopic surgery follow.

QUOTATIONS FROM THE FDA HEARING

"With the identified dangers and availability of safer forms, the FDA should caution the surgical community about the improper laparoscopic use of monopolar electrosurgery. It would be unconscionable to do otherwise."

"The risk of burns which precipitated the FDA restrictive recommendations in 1980 is still a very valid concern today. The basic complication of tissue damage due to burns really has not changed at all. Use of monopolar technology remains one of the inherent dangers that has not improved in the intervening 10 years since the initial FDA action."

"Even if we could retrain every surgeon, injuries due to the use of (monopolar) electrosurgery would not be eliminated. The principles of electrical flow dictates that the flow of electrons must travel to a return or disbursive electrode. It is during this transit that damage can occur."

"It was not until bipolar devices replaced the more hazardous unipolar electrodes that significant reduction in electrical injuries was observed."

"It is true that general surgeons do not appreciate the difference in risk between the use of electrosurgical units in an open abdomen, and the risk in an open abdomen versus the risk using the laparoscopic approach."

HEMOSTATIX manufactures a family of **BIPOLAR ENDOSCOPIC SCISSORS** that precisely convey electrical energy from one blade of the scissors to the other and only at the point of cutting to seal the tissues prior to being cut.

HEMOSTATIX manufactures a family of **ENDOSCOPIC PROBES** that rapidly attain and constantly maintain a preselected level of elevated temperature at every point on the operating portion of the probes, directly providing thermal energy to enhance tissue cutting and dissection.

HEMOSTATIX
SURGICAL INSTRUMENTS

"Unpredictable electrical flow (of monopolar currents) must satisfy basic electrical principles in completing a circuit. This will result in an irreducible number of injuries. Irreducible because the electrical flow is unpredictable. Of note is that most of the recorded injuries in the gynecological field in the 1970s, occurred to experienced operators, not interns, not residents."

"Electrosurgical techniques developed during open surgery do not translate well to the laparoscopic environment. Access to intra-abdominal structures is limited, and the application of the unipolar electrode may not be ideal. Under these circumstances electricity which follows the path of least resistance may spark or be transmitted from any part of the exposed metal delivery tip to adjacent non-target structures."

"Laparoscopic surgical visibility is limited to the field of view of the camera. This field of view is two-dimensional; depth perception is altered; and it can be difficult to judge distance between objects. In addition, magnification decreases the scope of the observed field. Tissue reactions just beyond the camera lens go unobserved. Smoke produced during laparoscopic surgery facilitates electrical discharge."

"Monopolar electrical devices must utilize our patient's body as a conductor. This conduction of electrical energy is unpredictable in its ultimate pathway. We can direct where electrical energy is targeted, but we cannot control its path of flow."

"Electrocautery's dangers are very deceptive. The damage to bowel occur at a distance from the site of dissection, so the surgeon is unaware that it has occurred during the procedure."

"As you know, the JAMA article a month-and-a-half ago, the editorial had a very interesting little comment...The three authors said in their first 381 cases they had two deaths, both from small bowel injuries."

"Electrosurgical injuries that can occur are very difficult to detect at the time of surgery. This is what adds to the fact that there are some latent bowel injuries that are not detected until approximately 72 hours postoperatively. When we are referring to these electrosurgical injuries, we are actually referring to the injuries associated with monopolar current not bipolar current."

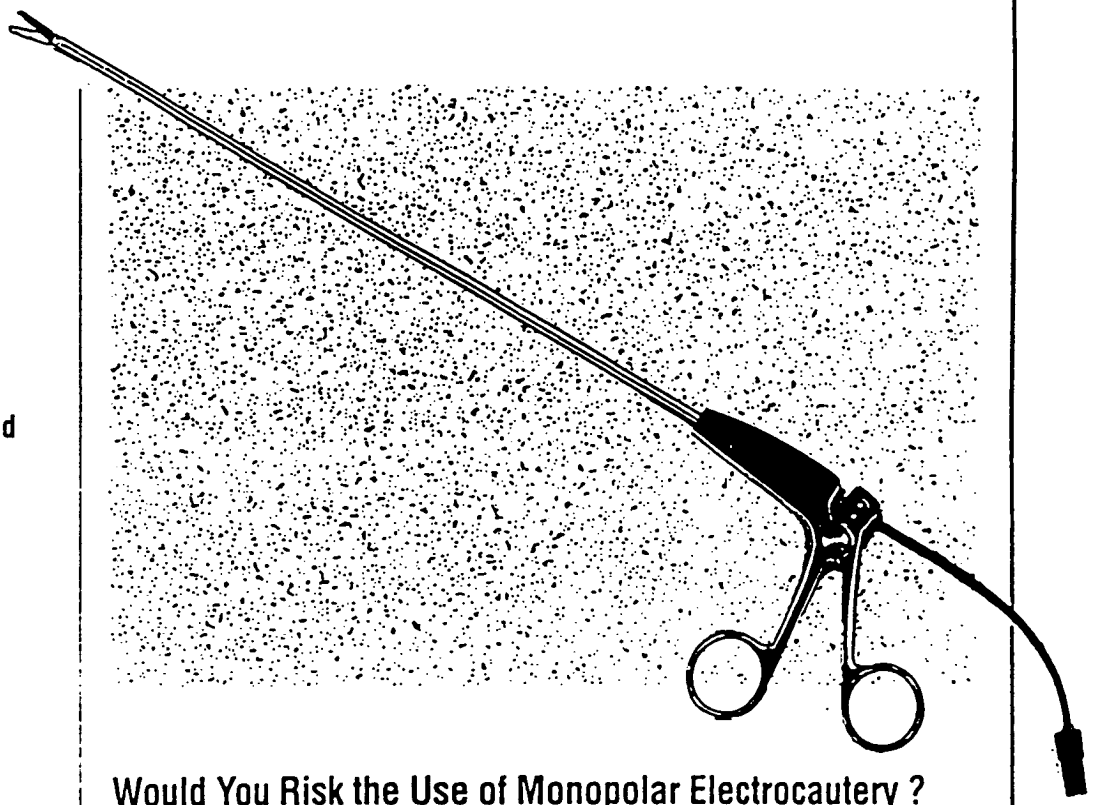
"We have identified the number of fatal bowel burn injuries that occurred in the 1970s, but we probably have no idea of the number of non-fatal, electrical burns that occurred during this same time frame."

"We have a lot of patients, they have prior surgery, they have adhesions We don't know what's under there, and we know that they have been putting holes in everything in sight, from the aorta back up to just simply the bowel. Then they find out about it two or three days later."

"Most experienced gynecologic laparoscopists do not like to use monopolar surgery. Only a small portion of the experienced laparoscopists use the modality routinely, and the percentage is continuing to decline via increased knowledge and familiarity with newer and safer forms."

SHAW Bipolar ENDOscopic Scissors

Straight, Curved, Hooked



Would You Risk the Use of Monopolar Electrocautery ? If You Had Something That Was...

- Safer
- Faster
- More Hemostatic
- Cost Effective

Enjoy the Benefits of

- Superior Thermally Enhanced Function
- One Instrument to Cut & Dissect
- Unique, Proprietary Technology

Available Soon

Increase

- Patient Safety
- Visibility—Less Plume
- Precision of Procedure

Avoid

- Aberrant Currents
- Laser Burns
- Injury to Bowel & Other Vital Structures

HEMOSTATIX
SURGICAL INSTRUMENTS

Less Invasive More Effective Hemostasis

SHAW Bipolar ENDOscopic Scissors

Straight, Curved, Hooked

HEMOSTATIX uses advanced proprietary technology to produce the unique SHAW Bipolar ENDOscopic Scissors. Most other endoscopic cutting or dissecting instruments currently available use monopolar electrical current which passes from the instrument through the patient's body to a plate. Such currents are known to be able to perforate bowel and cause damage to other vital structures, even at a distance from the operating site. Because Hemostatix Scissors are bipolar, electrical energy is delivered only from one jaw of the scissors to the other, and only at the point of cutting. Damage to neighboring and remote structures is not possible. Because they are bipolar, they provide exceptional hemostasis and greater precision: all of the energy is concentrated at the point of tissue cutting; no energy passes through other tissues and muscle stimulation does not occur.

The Principle

The patented technology of the SHAW Bipolar ENDOscopic Scissors enables high frequency electrical current to be precisely controlled, restricting the delivery of current solely to those tissues being cut and only at the point of closure of the scissor jaws. This precise delivery of the preselected quantity of power to only the chosen location provides the surgeon with three outstanding capabilities:

Exceptional Hemostasis—since all of the energy output is concentrated at the point of scissors cutting;

Greater Precision—since energy is not delivered to surrounding tissues and muscle stimulation does not occur; and,

Greater Safety — since there are no remote or aberrant electrical currents to cause damage to neighboring or distant vital structures as may occur with conventional monopolar electrosurgical devices.

The Instrument

The SHAW Bipolar ENDOscopic Scissors come in three blade configurations—straight, curved and hooked blades—with two mechanisms—single action and double action.

Each scissors is connected to the SHAW Hemostatic Surgery System 3-in-1 Controller Model 3000 by a light-weight cable. The 3-in-1 Controller provides precise hemostatic power continuously adjustable through a broad range. When not energized the scissors may also be used as cold endoscopic scissors.

The Benefits

- Increased Patient Safety
- More Precise Cutting and Dissecting
- Drier Field, Less Smoke Plume

HEMOSTATIX
SURGICAL INSTRUMENTS

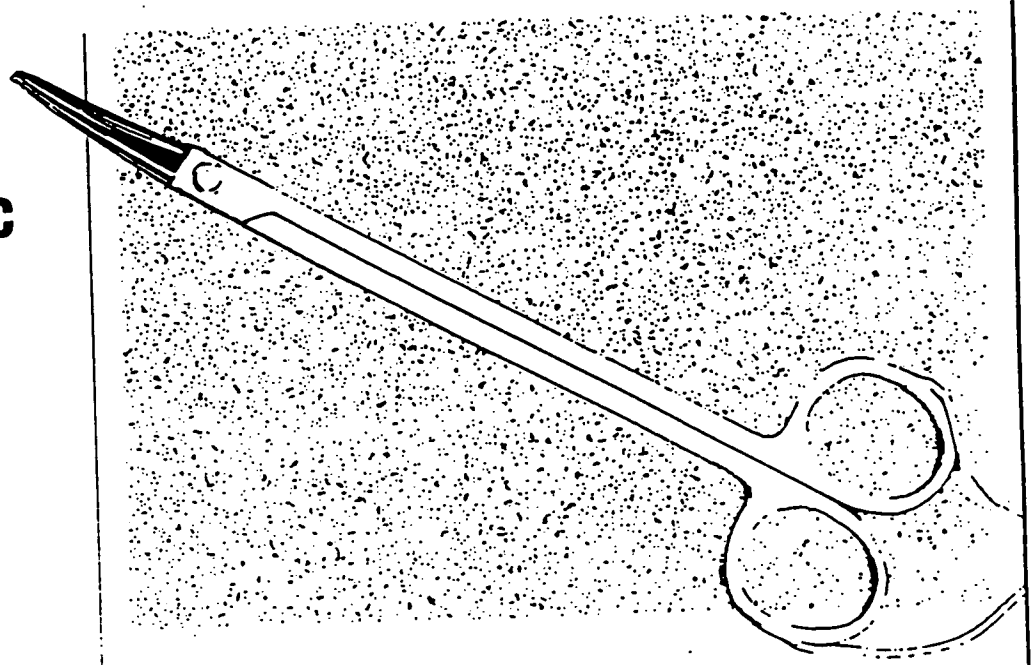
351 California Street
San Francisco, CA 94104
1-800-SCALPEL (1-415-781-0700)

Less Invasive More Effective Hemostasis

NEW
UNIQUE

SHAW Bipolar Hemostatic Scissors

All Common Scissors Configurations



Prevent Bleeding Before It Starts

Shorten Procedure Time

Enjoy the Benefits of

- Superior Thermally Enhanced Function
- No Aberrant Currents
- Increased Patient/Team Safety
- The Feel of a Fine Surgical Instrument

Available Soon

HEMOSTATIX
SURGICAL INSTRUMENTS

Precise Energy Delivery...Only Where You Cut

SHAW Bipolar Hemostatic Scissors

All Common Scissors Configurations

HEMOSTATIX uses advanced proprietary technology to produce these unique bipolar hemostatic dissecting scissors with all of the quality and feel of fine surgical scissors. Because they are bipolar, electrical energy is delivered only from one jaw of the scissors to the other and only at the point of closure of the scissor jaws where the tissue is being cut. Because they are bipolar, they provide exceptional hemostasis and greater precision: all of the energy is concentrated at the point of tissue cutting. No energy passes through other tissues and muscle stimulation does not occur.

The Principle

The patented technology of the SHAW Bipolar Hemostatic Scissors enables high frequency electrical current to be precisely controlled, restricting the delivery of current solely to those tissues being cut, and only at the point of closure of the scissor jaws. This precise delivery of the preselected quantity of power to only the chosen location provides the surgeon three outstanding capabilities:

Exceptional Hemostasis — since all of the energy output is concentrated at the point of scissors cutting;

Greater Precision — since energy is not delivered to surrounding tissues and muscle stimulation does not occur; and,

Greater Safety — since there are no remote or aberrant electrical currents to cause damage to neighboring or distant vital structures as may occur with conventional monopolar electrosurgical devices.

The Instrument

SHAW Bipolar Hemostatic Scissors are made of fine steel by German craftsmen. They are available in all of the conventional scissors configurations (Metzenbaum, Mayo, etc.) and in a range of sizes. Additional shapes and sizes may be specially ordered.

Each pair of scissors is connected to the SHAW Hemostatic Surgery System 3-in-1 Controller Model 3000 by a light-weight cable. The 3-in-1 Controller provides precise hemostatic power, continuously adjustable through a full range. When not energized, the scissors may also be used as cold surgical scissors.

The Benefits

- Less Bleeding, Drier Surgical Fields
- More Precise Surgery
- Shortened Procedure Time
- Less Post-Op Edema

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SURGICAL INSTRUMENTS

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San Francisco, CA 94104
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Precise Energy Delivery...Only Where You Cut